Amendments to the Drawings

The replacement attached drawing sheets include changes to FIGS. 1, 1A and 2, 2A. These sheets replace the original sheets including FIGS. 1, 1A and 2, 2A, respectively. FIGS. 1, 1A, 2, and 2A have been amended to designate the septum by the reference character "SEP"".

Attachment: Replacement Sheets

REMARKS

The above listed claim amendments along with the following remarks are fully responsive to the Office Action set forth above. In the Office Action, the Examiner has objected to the drawings for failing to comply with 37 CFR 1.84(p)(4) because the reference character "S" has been used to designate both a septum of a diseased heart in FIGS. 2 and 2A and a suture point on the diseased heart in FIG. 3A. The drawings were also objected because the reference character "S" has been used to designate both a septum of a healthy heart in FIGS. 1 and 1A and a suture point in FIG. 4A. Additionally, the Examiner objected to claim 35, 36 and 38 and rejected claims 18 and 32-41.

By this Amendment and Response, replacement drawing sheets including amended FIGS. 1, 1A, 2, and 2A are submitted, and the Specification is hereby amended to reflect the amendments to the drawings. Additionally, claims 35 and 36 have been amended to address formalities raised in the Office Action, and claim 38 has been canceled. No new matter is added by the foregoing amendments. Claims 18, 32-37, and 39-41 remain pending. Reconsideration and allowance of the specification, drawings and claims 18, 32-37, and 39-41 in view the amendments and the accompanying Remarks is respectfully requested.

Drawings

In the Office Action, the drawings were objected to as failing to comply with 37 C.F.R. § 1.84(p)(4). The Applicants submit herewith replacement drawing sheets including amended FIGS. 1, 1A, 2, and 2A, in which the septum is now designated by the reference character "SEP"'. Additionally, the paragraph at page 6, lines 24-25 of the specification is hereby amended to reflect the foregoing amendments to the drawings. The Applicant believes that this fully addresses the objections to the drawings. Reconsideration and withdrawal of the objections to the drawings is respectfully requested.

Claim Objections

Claims 35, 36 and 38 are objected to because of claim informalities. By this Amendment, claim(s) 35 and 36 have been amended to address these informalities, and claim 38 has been canceled. The Applicant respectfully requests reconsideration and withdrawal of the objections to claims 35 and 36.

Claim Rejections – 35 USC § 103(a)

Claims 18 and 32-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,224,540 B1 ("Lederman") in view of U.S. Patent 5,336,253 ("Gordon"). As noted above, by this Amendment and Response, claim 38 has been canceled. The Applicant respectfully traverses as to the remaining claims.

Independent claim 18 recites a method for treating cardiac disease of a heart, the method comprising placing a device on the heart, the device comprising compliant biocompatible material configured to engage a surface of the heart to passively constrain circumferential expansion of the heart. Claim 18 further recites passing an electrical current to the heart with said current selected to apply an electrical therapy to said heart.

The Lederman patent discloses, in relevant part, a passive "girdle" for treating ventricular dilatation associated with congestive heart failure. As disclosed, the girdle of the Lederman patent constrains ventricular dilatation during diastole and does not affect the action of the ventricle during diastole. The Office Action acknowledges that the Lederman patent fails to disclose passing an electric current to the heart with said current selected to apply an electrical therapy to said heart, as recited in independent claim 18. The Office Action relies, however, on the Gordon patent as disclosing this step. The Applicant respectfully asserts that the Office Action has improperly combined the teachings of the Lederman and Gordon patents.

The Gordon patent is directed to pacing and cardioversion lead systems for use in the detection and control of cardiac bradyarrhythmias and tachyarrhythmias by the application of electric stimuli to the heart. The Gordon patent makes no mention of treating congestive heart failure, much less provide any teaching or suggestion regarding constraining ventricular dilatation. Nevertheless, in combining the teachings of the Lederman and Gordon patents, the Office Action asserts that "[s]ince both Lederman et al and Gordon et al both apply a therapy to a diseased heart, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lederman et al to include the application of electrical therapy to the heart." The Applicant respectfully submits that the Office Action's apparent rationale for combining the teachings of the Lederman and Gordon patents – i.e., that both relate to "apply[ing] a therapy to a diseased heart" – fails to support a *prima facie* case of obviousness.

The Examiner bears the initial burden of factually supporting any *prima facie* case of obviousness. *See* M.P.E.P. § 2142. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation to combine the teachings of the cited references. This suggestion or motivation to combine the cited references can be found either in the nature of the problem to be solved, the teachings of the references themselves, or the knowledge of persons of ordinary skill in the art. *See In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998). There must also be a reasonable expectation of success. *See* M.P.E.P. § 2143. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be both found in the prior art, not in the Applicant's disclosure. *See id.* (citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

The Applicant respectfully believes that the Office Action does not establish the necessary motivation or suggestion to combine or modify the teachings of the Lederman and Gordon patents. Even if the teachings of the Lederman and Gordon patents could be combined, which is not clear from their respective disclosures, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *See* M.P.E.P. § 2143.01.III (citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990)). Here, neither of the cited references includes the necessary suggestion or motivation to modify the teachings of the Lederman patent as stated in the Office Action. Moreover, the mere fact that the Lederman and Gordon patents relate, in a general sense, to applying therapy to a heart does not provide any teaching, motivation, or suggestion to combine the therapies they disclose, particularly where, as here, the references disclose very different therapies.

Indeed, the subject matter of the Lederman patent is very different from that of the Gordon patent. The Lederman patent is directed solely to a passive girdle for constraining ventricular dilatation of the heart and thereby treating congestive heart failure. In stark contrast, the Gordon patent is directed solely to lead systems for delivering pacing, cardioversion, and defibrillation shocks to the heart for treating cardiac arrhythmias. Neither the Lederman patent nor the Gordon patent teaches or suggests the desirability of combining its disclosed therapeutic technique and devices with any other type of therapy. Certainly, nothing in either of these references teaches or suggests the desirability of combining mechanically constraining

ventricular dilatation using a passive girdle, as disclosed in the Lederman patent, with the application of a pacing, cardioversion or defibrillating shocks as disclosed in the Gordon patent.

Moreover, the Lederman patent actually teaches away from combining its girdle with other types of therapies that would affect ventricular action of the heart. As disclosed in the Lederman patent, the girdle operates to constrain ventricular dilatation during diastole, but "does not effect the action of the ventricle during systole." Col. 3, ll. 7-11. Thus, the Lederman patent teaches away from combining the disclosed girdle with other therapies that would affect the action of the ventricles during systole.

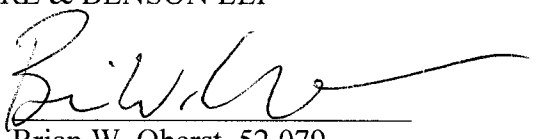
For at least these reasons, the Applicant respectfully submits that neither the Lederman nor the Gordon patents, whether alone or in combination, render independent claim 18 obvious. The Applicant therefore believes that claim 18, and also claims 32-37 and 39-41 which depend from claim 18, are patentable over the prior art of record. The Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a)

Conclusion

In conclusion, all pending claims 18, 32-37, and 39-41 are believed to be in condition for allowance. The Applicant respectfully requests that a Notice of Allowance be issued in this case.

Respectfully submitted,

FAEGRE & BENSON LLP

By: 

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